DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 3, 2014

Eco Medi Glove SDN BHD
Mr. Suresh Kumar
Quality Assurance Manager
Lot 23826 Jalan Tembaga Kuning
Kamunting Raya Industrial Estate
Taiping, Perak Darul Ridzuan 34600
MALAYSIA

Re: K141590
Trade/Device Name: EMG Blue Nitrile Medical Examination Glove Powder Free (Non-Sterile)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: August 08, 2014
Received: August 12, 2014

Dear Mr. Kumar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Device
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Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141590

Device Name
EMG Blue Nitrile Medical Examination Gloves Powder Free (Non Sterile)

Indications for Use *(Describe)*
A Patient Examination Glove is a disposable device intended for medical purposes that is worn on the examiner's hands or fingers to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K141590

Appendix 2

510(K) Summary
EMG Blue Nitrile Medical Examination Gloves Powder Free
(Non Sterile)

1.0 Submitter :

Company Name : ECO MEDI GLOVE SDN. BHD

Company Address : Lot 23826,Jalan Tembaga Kuning
Kamunting Raya Industrial Estate,
34600,Kamunting Perak
Malaysia.

Contact Person : Mr Suresh Kumar

Telephone No : 603-60283033

Email : suresh@ecomediglove.com.my

2.0 Preparation Date : 22nd August 2014

3.0 Name of the Device

Trade Name / Proprietary Name : EMG Blue Nitrile Medical Examination Gloves Powder Free (Non Sterile)

Device Name : Nitrile Patient Examination gloves

Device Classification Name : Patient Examination gloves (21 CFR 880.6250)

Device Class : Class I

Product Code : Nitrile-LZA

4.0 Identification of The Legally Marketed Device :

Class I patient Examination gloves,Powder Free,LZA which meets all the requirement of ASTM D 6319-10 and FDA 21 CFR 880.6250.It is equivalent to K 100603, RS Safe Blue Nitrile Medical Examination Gloves Powder Free (Non-Sterile)

Appendix 2

5.0 Description of Device

Blue Nitrile Medical Examination gloves powder free, non sterile, as described in this 510(k) Notification is substantially equivalent to the current class I patient examination gloves with product Code LZA (21CFR 880.6250). It meets all the specifications in ASTM D6319-10, Standard specification for Nitrile Examination Gloves. They are made nitrile from nitrile latex compound,Blue colour, powder free and non sterile.

6.0 Intended use of the Device

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. It is for over-the-counter use.

7.0 Summary of the Technological Characteristics of the Device compared to the Predicate Device for substantial equivalent discussion

There is no different technology characteristics compared to the predicate device . Gloves are made from nitrile latex compound, Blue colour, powder free and non sterile. It is equivalent to K 100603, RS Safe Blue Nitrile Medical Examination Gloves Powder Free (Non-Sterile)

Appendix 2

Characteristics	**Acceptance Criteria**	**EMG Blue Nitrile Medical Examination Gloves (Powder Free)**	**RS Blue Nitrile Medical Examination Gloves Powder Free (Non-Sterile) K 112928**
Product Code	LZA	LZA	LZA
Intended use	A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The device is for over-the-counter use.Intended use	A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The device is for over-the-counter use.	A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The device is for over-the-counter use.
Material use	Not made from Natural Rubber Latex	Nitrile latex compound	Nitrile latex compound
Colour	Blue	Blue	Blue
Sterility	Non sterile	Non sterile	Non sterile
Dimensions	Overall Length (mm) = 230mm Width (± 5mm) **Size S = 85mm** **Size M = 95mm** **Size L = 105mm** **Size XL = 115mm** Thickness at Palm (mm) = 0.05min Thickness at Finger Tip (mm) = 0.05min	Meets ASTM D6319-10	Meets ASTM D6319-10

Appendix 2

Physical properties	**Before Ageing** Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 500min **After Aging at 70°C for 168 hrs @ 100°C for 22 hrs** Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 400min	Meets ASTM D6319-10	Meets ASTM D6319-10
Freedom from pinholes	AQL 2.5 Inspection Level G-1	Meets ASTM D6319-10	Meets ASTM D6319-10
Residual Powder	$\leq$ 2.0 mg/pc	Meets ASTM D6319-10	Meets ASTM D6319-10
Biocompatability test-Primary Skin Irritation Test		Under the conditions of the study, not an irritant and Under conditions of the study , not a sensitizer	Under the conditions of the study, not an irritant and Under conditions of the study , not a sensitizer
Dermal Sensitization Assay		Under the conditions of the study, not an irritant and Under conditions of the study , not a sensitizer	Under the conditions of the study, not an irritant and Under conditions of the study , not a sensitizer

Appendix 2

EMG Blue Nitrile Medical Examination Gloves Powder Free posting the following technological characteristics

compared to ASTM or Equivalent standards:

Acceptance Criteria	**Standards**	**Device Performance EMG Blue Nitrile Medical Examination Gloves Powder Free (Non-Sterile)**
Dimension Overall Length (mm) = 230mm Width (± 5mm) **Size S = 85mm** **Size M = 95mm** **Size L = 105mm** **Size XL = 115mm** Thickness at Palm (mm) = 0.05min Thickness at Finger Tip (mm) = 0.05min Dimension	Meets ASTM D6319-10	Meets ASTM D6319-10
Before Ageing Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 500min **After Aging at 70^{o}C for 168 hrs @ 100^{o}C for 22 hrs** Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 400min	Meets ASTM D6319-10	Meets ASTM D6319-10

Appendix 2

Freedom from pinhole AQL 2.5 Inspection Level G-1	ASTM D 6319-10	Specification within ASTM D6319-10
Residual Powder ≤ 2.0 mg/pc	ASTM D 6319-10	Specification within ASTM D6319-10
Biocompatability	Primary Skin Irritation Test Consumer Product Safety Commission, Title 16, Chapter II, Part 1500	Under the conditions of the study, not an irritant and Under conditions of the study , not a sensitizer
	Dermal Sensitization Assay- ISO 10993-10:2010(E)	Under the conditions of the study, not an irritant and Under conditions of the study , not a sensitizer

8.0 Conclusion

The Conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally Marketed device